K101311

Philips Medical Systems Nederland B.V.
Veenpluis 4-6, 5684-PC, Best
The Netherlands

PHILIPS

# 510(k) Summary

SEP 30 2010

The following information is submitted in accordance with the requirements of 21CFR 807.92.

**Identification of manufacturer**

Company:..... Philips Medical Systems Nederland B.V.
Address:..... Veenpluis 4-6,
5684-PC, Best, The Netherlands
Registration number:..... 3003768277

**Identification of submitter**

Name:..... Lynn Harmer
Position:..... Senior Manager, Regulatory Affairs
Telephone:..... (425) 487-7312\
Fax: (425) 487-8666
Date prepared:..... May 7, 2010

**Device identification**

Trade name:..... Philips
Device name:.....EP navigator
Regulation description:..... Picture archiving and communications system
Regulation number:..... 21CFR 892.2050
Class:..... II
Product code:..... 90L--LZ

**Legally marketed devices**

Trade names:..... Philips EP navigator, Philips Brilliance CT,
Philips Allura 3D-CA, Philips Integris 3D-RA,
Philips Xper CT, GE Innova Vision Applications
Manufacturer:..... Philips and GE
510(k) numbers:..... K062650, K042293, K042334, K040254, K060749,
K092639

**Device description**

EP navigator image software processing algorithms are executed on a PC based hardware platform, which can perform the following functions:

- segment previously acquired DICOM 3D CT or other image data.(the acquisition of the image data from a rotational angiogram is known as 3D atriography (3D ATG))
- superimpose the segmented 3D CT or other dataset on a live fluoroscopic X-ray image of the same anatomy, obtained on a Philips Allura Xper FD angiography X-ray system,
- register the segmented 3D CT or other data with live fluoroscopic X-ray images obtained on a Philips Allura Xper FD angiography X-ray system for specified procedures.
- The 3D segmented data set can be displayed with a color map annotation received from an external source.
- position visual markers on the 3D volume
- visualize the inside of the 3D volume (EndoView)
- certain buttons on the user interface control EP Logix functions;
- visual marker positions are transmitted to EP Logix;
- color map information is received from EP Logix.

**Intended use**

EP navigator is intended to enable users to segment previously acquired 3D CT or other datasets and overlay and register these 3D segmented data sets with live fluoroscopy X-ray images of the same anatomy in order to support catheter/device navigation. The 3D segmented data set can be displayed with a color map annotation received from an external source.

**Indications for Use**

**Medical purpose** EP navigator is intended to provide navigation support for intra-cardiac instruments, such as catheters and guidewires, during the interventional treatment of heart rhythm disorders, by overlaying acquired and segmented 3D anatomical image data over live fluoroscopic X-ray images of the same anatomy.

**Patient population** EP navigator is intended to be used with patients who suffer from heart rhythm disorders and who are capable of undergoing a procedure guided by X-ray fluoroscopy.

**Contact with body part / tissue type** The heart and surrounding tissue are illuminated by X-ray fluoroscopy (by the Allura Xper system).

**Operator profile** The Operator is a Radiologist or Cardiologist who is fully skilled and responsible for sound clinical judgment and for applying the best clinical procedure. The Operator may also be a nurse assisting who is authorized by the Radiologist or Cardiologist.

**Application** EP navigator is to be used in a controlled environment in the context of a control room of a Cathlab. The system is connected to an Allura Xper system.

**Contra-indications** Within the mentioned patient population, there are no contra-indications.

**Technological characteristics**

EP navigator image software processing algorithms are executed on a PC based hardware platform

**Summary of testing**

EP navigator 3 complies with standards as detailed in annex 009 of this premarket submission. Clinical evaluation was performed to show safety and effectiveness to of EP-Navigator in the intended clinical environment. Non-clinical verification and validation tests were performed relative to the requirement specifications and risk management results, specifically including software verification, validation and DICOM conformance testing. Corresponding clinical evaluation report and test results are included in this submission.

Conclusion:..... EP-Navigator is substantially equivalent to the currently legally marketed devices.

This opinion is based on the following:

- EP navigator does not introduce new indications for use,
- EP navigator has the same technological characteristics as the predicate devices,
- EP navigator does not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems
22100 Bothell Evert Highway
BOTHELL WA 98041-3003

SEP 30 2010

Re: K101311
Trade/Device Name: EP Navigator
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 10, 2010
Received: May 11, 2010

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K101311

Appendix 005

PHILIPS

Indications for Use Statement

## Device Name

EP navigator

## Indications for Use

SEP 30 2010

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| Prescription Use __yes____ | AND/OR | Over-The-Counter Use __No___ |
|---|---|---|
| (Part 21 CFR 801 Subpart D) | | (21 CFR 807 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101311